

REMARKS

Claims 1, 3-20, and 22-30 are currently pending in the application. Claims 1, 17, and 27 are in independent form, and have been amended to more clearly set forth that there are no openings from the downflow lumen that are exposed to a patient. Support for this amendment can be found in Figures 4 and 5, as well as paragraphs [0046]-[0049]. No new matter has been added.

Claims 1, 3, 5-10, 14, 15, 17, and 22-26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,788,676 to Yoon in view of U.S. Patent No 5,993,471 to Riza, et al., and further in view of U.S. Patent No. 4,180,068 to Jacobsen, et al. Specifically, the Office Action holds that Yoon discloses a trocar having an insert end with a housing wherein a pair of universal seals are positioned in the proximal and distal ends of the chamber to provide an air and fluid tight seal when engaging or not engaging an instrument but fails to disclose perpendicular diaphragms, and Riza, et al. teaches two deformable diaphragms having slits that are perpendicular with respect to one another. The combination of Yoon and Riza, et al. fails to disclose a downflow lumen having an outlet opening into an instrument lumen and an inlet port opposite thereto. The Office Action holds that Jacobsen, et al. discloses a trocar including lumens disposed therein for irrigation of fluid through a downflow lumen and into the instrument lumen that removes substances in the instrument lumen. Therefore, the Office Action holds that it would have been obvious to one skilled in the art to provide consecutive diaphragms having perpendicular slits to enhance sealing structure and to provide the device with a downflow lumen, as taught by Jacobsen, et al. to simultaneously introduce and withdraw fluids from the body of a patient. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Yoon in view of Riza, et al. and Jacobsen, et al. is respectfully requested.

"Any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed"; however, that reason must be present for the combination to be obvious. *KSR Intern Co. v. Teleflex*, 127 S. Ct. 1727, 1742, U.S. (2007). This requirement was confirmed in *Takeda Chem. Indust., et al. v. Alphapharm*, No. 06-1329 (Fed. Cir. 2007).

"The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit." MPEP Section 2143.

"The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art." *KSR International Co. v. Teleflex Inc.*, 83 USPQ2d 1385, 1395 (2007) and MPEP Section 2143.

As previously stated, the goal of the device of Yoon is to prevent damage to universal seals by preventing contact with instruments when they are inserted or withdrawn in the endoscopic portal. More specifically, the universal seals 16a and 16b are "disposed in the main body 26 in axially spaced relation to one another." Col. 6, lines 3-4. In other words, the universal seals are in alignment with one another in order to let an instrument through the portal. One seal is opened allowing passage of the instrument while the other seal remains closed to prevent leakage into the portal. Yoon does not disclose seals that are perpendicular to each other instead of aligned with each other as in the present invention. Yoon further does not disclose a downflow lumen having an outlet into an instrument lumen. Yoon does not provide any reason to add these features to his device.

Applicants agree that Riza discloses a split seal 44 and a second seal defining a plane which is perpendicular to the plane defamed by the slit 52 of the split seal 44 that provides an enhanced sealing structure for a shaft of a surgical instrument inserted through both of the split seals. (Col. 7, lines 50-57).

Jacobsen, et al. discloses a "single-tube double-lumen catheter through which fluids may be simultaneously introduced into and withdrawn from the body of a patient." Col. 2, lines 1-6. Tubes 8 and 12 communicate with primary tube 2 through openings 9 and 13 on the primary tube. Between the branching tube 8 and the distal end of the primary tube 2 is an opening 20 in the wall of the primary tube that allows fluid to flow from the body of the patient into the primary tube. A trocar 24 divides the interior of the primary tube 2 into two lumens 25 and 27. Looking at Figures 1-4 of Jacobsen, et al., it is evident that the device cannot function as required in the present invention. Adding the lumens of Jacobsen, et al. to the combination of Yoon and Riza, et al. would function in the opposite manner of the present invention. The lumens of Jacobsen, et al. are not separate from the instrument lumen, and are only formed when the trocar is present, or an instrument is present, in the primary tube. The lumens are also not used to flow fluid through the instrument lumen to remove harmful substances, but rather are open to the patient through openings 9 and 20 in order to deliver fluid to or remove fluid from the patient. This is completely opposite to the function of the downflow lumen in the present invention. Fluid could not be used to remove substances in the instrument lumen of Jacobsen, et al. because it would just exit through either openings 9 or 20 *in the patient*, and not flow through the instrument lumen up to the outlet port which is located outside of the body of the patient as described in the present invention.

The downflow lumen of the present invention is described in the following paragraphs:

[0046] The second lumen a down flow lumen 34, extends from the body 14 and through the wall of the trocar 10. An outlet 40 opens proximate to the instrument lumen 30. The down flow lumen 34 is made of any resilient material that is fluid tight, and is capable of having a fluid flow there through.

[0047] The body 14 of the trocar 10 preferably includes an inlet port 36 fluidly connected to the down flow lumen 24. The inlet port 36 enables the flow of an inert fluid through the port 36 into the down flow lumen 40 within the trocar 10. Additionally, the body 14 includes at least one outlet port 38. The outlet port 38 allows air trapped within the body 14 and neck 12 of the trocar 10 to escape from the trocar 10.

[0048] In use, an inert fluid, such as saline, is flowed into the down flow lumen 34, via the inlet port 26, out the outlet port 40 proximate to the instrument lumen 30 of the trocar 10. The fluid contacts any substances, such as air bubbles, that are present within the instrument lumen 30 of the trocar 10. The air bubbles then flow with the fluid up the instrument lumen 30 to the outlet port 38. In other words, fluid is constantly forcibly passed through the instrument lumen 30 of the trocar 10 such that any air bubbles found within the trocar 10 are captured within the fluid and the flow of the fluid carries the air bubbles away from the insertion end 16 of the trocar 10.

[0049] Of vital importance in surgery is that air not be allowed to enter the bloodstream of a patient. This is most critical when beating heart cardiac surgery is being performed because the insertion of oxygen into a blood stream can cause a fatal problem for the patient. Thus, the flowing of the fluid into the instrument lumen 30 of the trocar 10 enables air, and any other substances present in the trocar 10, to

be removed from the patient, thereby preventing air or other foreign substances from entering the blood stream of a patient.

The downflow lumen only having an opening into the instrument lumen is critical to the function of the present invention, as the reason for the downflow lumen being present is to remove any harmful substances that can be present in the instrument lumen from entering the patient. Having extra openings in the lumen as shown in Jacobsen, et al. would defeat the purpose of including the downflow lumen in the present invention. Thus, combining Yoon, Riza, et al., and Jacobsen, et al. would not result in the present invention.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claims 4, 18, and 19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,788,676 to Yoon in view of U.S. Patent No 5,993,471 to Riza, et al., and further in view of U.S. Patent No. 4,180,068 to Jacobsen, et al., and further in view of U.S. Patent No. 5,658,298 to Vincent, et al. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Yoon in view of Riza, et al., Jacobsen, et al., and Vincent, et al. is respectfully requested.

As stated above, the combination of Yoon, Riza, et al., and Jacobsen, et al. does not result in the invention as claimed in the presently amended independent

claims. Therefore, adding Vincent, et al. to this combination does not arrive at invention as defined in the dependent claims.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claims 11-13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,788,676 to Yoon in view of U.S. Patent No 5,993,471 to Riza, et al., and further in view of U.S. Patent No. 4,180,068 to Jacobsen, et al., and further in view of U.S. Patent No. 5,968,060 to Kellogg. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Yoon in view of Riza, et al., Jacobsen, et al., and Kellogg is respectfully requested.

As stated above, the combination of Yoon, Riza, et al., and Jacobsen, et al. does not result in the invention as claimed in the presently amended independent claims. Therefore, adding Kellogg to this combination does not arrive at invention as defined in the dependent claims.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claim 16 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Yoon in view of Riza, et al. and further in view of Jacobsen, et al., and in further view of U.S. Patent No 5,256,149 to Banik, et al. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Yoon in view of Riza, et al., Jacobsen, et al., and Banik, et al. is respectfully requested.

As stated above, the combination of Yoon, Riza, et al., and Jacobsen, et al. does not result in the invention as claimed in the presently amended independent claims. Therefore, adding Banik, et al. to this combination does not arrive at invention as defined in the dependent claims.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claims 27 and 28 stand rejected under 35 U.S.C. § 102(b), as being anticipated by Jacobsen, et al. Specifically, the Office Action holds that Jacobsen, et al. discloses the method steps including the insertion of an instrument (24) into the lumen of a trocar catheter having substance removing means wherein irrigation of fluid is performed through a downflow lumen (27) and into the instrument lumen (16) and withdrawal of fluids is performed through the opening (20) and into the instrument lumen (25). Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by Jacobsen, et al., as applied to the claims, is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

As explained above, the lumens in Jacobsen, et al. function opposite to those in the present invention as they allow for fluid flow into and out of a patient. Furthermore, Applicants have more clearly distinguished in the claims that any substance that is in the instrument lumen or in the downflow lumen does not come in contact with the patient.

Therefore, since Jacobsen, et al. does not disclose downflow lumens that **prevent substances from entering the patient** as set forth in the presently pending independent claim 27, the claims are patentable over James and reconsideration of the rejection is respectfully requested.

Claim 29 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Jacobsen, et al. in view of Yoon. The Office Action holds that James discloses all of the limitations previously discussed except for the method step of sealing the lumen. The Office Action holds that it would have been obvious to provide the trocar of James with sealing means as taught by Yoon. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over James in view of Yoon is respectfully requested.

As stated above, Jacobsen, et al. does not disclose all of the required elements of the presently pending independent claims of having downflow lumens that prevent substances from entering the patient. Combining Yoon with Jacobsen, et al. does not make up for the deficiencies in either reference.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claim 30 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Jacobsen, et al. in view of Kellogg. The Office Action holds that Jacobsen, et al. fails to teach agitation means, but it would have been obvious to have provided James's trocar with vibrating means as taught by Kellogg. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Jacobsen, et al. in view of Kellogg is respectfully requested.

As stated above, Jacobsen, et al. does not disclose all of the required elements of the presently pending independent claims of having downflow lumens that prevent substances from entering the patient. Combining Kellogg with Jacobsen, et al. does not make up for the deficiencies in either reference.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above, and the prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,
KOHN & ASSOCIATES, PLLC

/Laura S. Dellal/
Laura S. Dellal, Reg. No. 61,919
Customer No.: 48924

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/Natalie Zemgulis/
Natalie Zemgulis